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Evaluation of a care pathway for patients with long-term pain after knee replacement

STAR INTERVENTION MANUAL

TABLE OF CONTENTS

PURPOSE OF THE MANUAL

This training manual is for the Extended Scope Practitioners (ESPs) who are delivering the STAR intervention to participants who have been allocated to the intervention arm of the trial. This guidance covers the delivery of the intervention, and is divided into two sections:

- Part 1: Delivery and organisation of the assessment clinics
- Part 2: Delivery and organisation of the follow-up telephone calls

OVERVIEW OF THE TRIAL

The aim of this trial is to evaluate the clinical effectiveness and cost-effectiveness of the STAR care pathway for patients with long-term pain after total knee replacement.

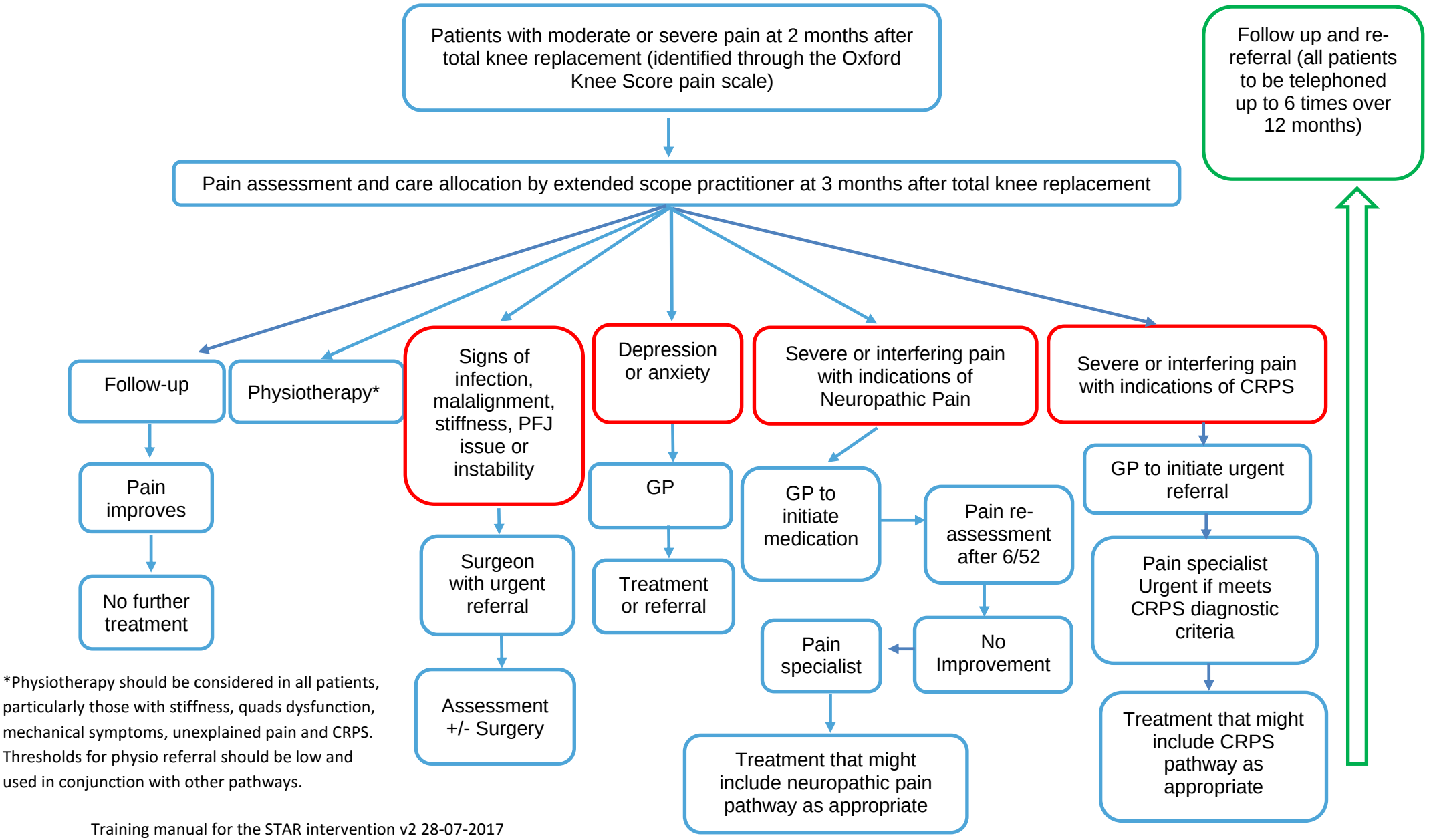
A total of 380 patients will be recruited into the trial. Recruitment will begin in September 2016 and will continue for 30 months. Two thirds of patients will be randomised to the intervention group. Patients will have already provided consent to participate in the trial, therefore additional consent for the assessment appointment is not required.

Patients will be recruited at 3 months after total knee replacement because of osteoarthritis. Recruited patients will have moderate or severe pain at 3 months after total knee replacement. Patients will then be randomised into the intervention group or usual care group. Patients in the usual care group will receive the usual care they would receive at their hospital for post-operative pain. Patients in the intervention group will receive their usual care as well as being invited to participate in the STAR intervention. An overview of the STAR intervention is provided overleaf. The STAR intervention has two components:

- One face-to-face assessment clinic appointment with an ESP
- Up to 6 follow-up telephone calls from the ESP over the next 12 months

An overview of the STAR intervention is provided in the flow diagram overleaf. All participants in the trial will be asked to complete questionnaires at recruitment and then 6 months and 12 months after randomisation. These will be administered by the research

team. Our primary outcomes are pain severity and pain interference at 12 months after randomisation.



*Physiotherapy should be considered in all patients, particularly those with stiffness, quads dysfunction, mechanical symptoms, unexplained pain and CRPS. Thresholds for physio referral should be low and used in conjunction with other pathways.

PART 1: THE ASSESSMENT CLINIC

OVERVIEW OF THE ASSESSMENT CLINIC

Participants randomised to receive the STAR intervention will be invited to attend one face-to-face assessment clinic appointment with an ESP at the hospital. This section provides an overview of the STAR intervention.

Who will attend the assessment clinic?

Patients invited to an assessment clinic appointment will be approximately 3 months after a total knee replacement because of osteoarthritis. They will be invited for an assessment because they have reported pain in their replaced knee that is moderate-severe in intensity (defined as a score of 0-14 out of 28 on the Oxford Knee Score pain scale).

When should patients attend the assessment clinic?

Patients will be offered an assessment appointment as soon as possible after randomisation, ideally within one week. Participants should have attended a clinic appointment by four months post-operative. If this is not possible, a protocol deviation form should be completed citing the reasons and reported the trial manager. Each case will be reviewed individually by the CI (or delegated person).

Before the assessment clinic

You will have a regular STAR assessment clinic slot into which patients will be booked. The booking of patients into clinic slots will be conducted by the research team. Patients will be provided with information about what to expect from the appointment prior to attending the clinic (see Appendix 1 for the Patient Information Leaflet).

How long is the clinic appointment?

Each patient will be allotted a one hour appointment. In addition, they will need to be x-rayed if this has not been performed as part of their standard care.

Set up of the clinic room and equipment

The clinic room will need to have a couch for some of the physical examinations. You will have been provided with a goniometer which should be used for the assessment of knee

range of motion. A blood sample will need to be taken to assess for CRP levels. This will be conducted and sent to the laboratory by the researcher or a clinic nurse.

Staffing of the clinics

A member of the research team will be present during the clinic to provide support to you and the patients. Specifically, they will provide you with the details of the patients booked into the clinic. They will ensure that patients complete the assessment questionnaire and bring it into the clinic room with them. They will take the blood sample and provide you with the clinic notes, if available.

Paperwork for the assessment clinic

Paperwork for each patient attending an assessment clinic includes:

- Patient's clinical notes
- Assessment proforma
- Assessment questionnaire
- Template referral letter

Every effort should be made by the researcher for clinical notes to be available at the time of the clinic assessment. Where full notes are unavailable, the most recent relevant clinic letters and a copy of the operation note should be made available to you by the researcher.

At the beginning of the clinic, a member of the research team will provide you with an assessment proforma for you to complete for each patient you see (Appendix 2). The researcher will then collect the completed assessment proformas from you at the end of the clinic. The following sections of the training manual provide a detailed overview of the assessment clinic processes and procedures, including guidance on appropriate referrals to services. The structure of this section follows that of the assessment proforma.

In addition, patients will be asked to complete an assessment questionnaire prior to seeing you (Appendix 3). This questionnaire includes questions about pain severity and interference (Brief Pain Inventory [BPI]), neuropathic pain (DN4 and PainDETECT) and depression and anxiety (Hospital Anxiety and Depression Scale [HADS]). The researcher will score these questionnaires and write the scores on the assessment proforma.

You will also be provided with a template referral letter for you to modify for each patient (Appendix 4).

ASSESSMENT PROFORMA: ADMINISTRATIVE DETAILS

Please ensure that you complete the administrative details at the beginning of the assessment proforma. These questions ask for details about yourself, the date of the clinic, the appointment start and end time, whether x-rays were conducted, the time taken for the x-rays (if the patient does not return to clinic after having the x-rays, then the time on the radiograph can be used as the time the patient returned from x-ray), patient name, patient mode of transport, patient travel time and whether the patient took time off work for the appointment.

ASSESSMENT PROFORMA SECTION 1: PAIN REPORT

General approach

The assessment and management of patients in pain after knee replacement can at times be extremely challenging. In the context of this assessment it is important to maintain an open and empathic approach, to give patients the opportunity to talk, and an opportunity to share their experiences and concerns.

This appointment may be the first opportunity that a patient has had to discuss their experiences so far and previous studies and pilot data have shown us that patients generally find this extremely valuable. It is appropriate and important to emphasise that some pain/discomfort is a normal part of the healing process but also not to downplay their experiences and reported level of symptoms.

Many patients will have formulated thoughts or strong opinions as to the likely origin of their symptoms which may or may not be accurate. Dismissal of such theories can in some cases be unhelpful and a supportive, careful, open-minded approach is perhaps more

appropriate. Reassurance and a positive approach is often well received and is particularly important for patients with an element of self-blame.

General history and information

Please ask the patient about: which surgeon performed their knee replacement; the date of surgery; what the experience of surgery was like; particular problems around the time of surgery (if any); their experience of recovery so far; brief summary of general health and comorbidities; and finally, a brief summary of social circumstances (home environment and degree of support). Please record a summary of chronological events following surgery: problems, concerns, treatment given so far e.g. any antibiotics (from whom), interventions, further surgery etc. Please also ask whether they have had previous knee surgery on the same knee or if they have had a TKR on the contralateral side. Please summarise the patient's answers in the free-text box on the assessment proforma.

Pain compared to pre surgery

Please obtain a description of pain prior to surgery – onset, duration, nature and site. Enquire about the impact of pre-surgery pain on lifestyle and level of function.

Then move on to ask about post-surgery pain:

- Is the pain the same or different to the pre-operative pain?
- Is the pain in the same location as the pre-operative pain?
- Is it better or worse?
- Duration, nature, aggravating factors and site of pain
- Has pain intensity post-surgery been consistent - is it improving, static or worsening?

Relate these discussions and findings to the BPI severity and interference scores as this gives an indication for pain severity and the level of interference of this pain to the patient.

Pain pattern

It is important to delineate the type of pain and get a feeling of whether the pain is mechanical, activity-related or has features consistent with neuropathic pain.

Features of neuropathic pain may include pain that is unchanged by surgery, pain from which there is no relief despite rest and analgesia, pain that is diffuse and hard to localise, pain that radiates towards or away from the knee, feelings of pressure, numbness, sensitivity, burning, stinging, or rigidity. Ensure you consider these alongside the scores of the DN4 and PainDETECT (these are screening tools for neuropathic pain and further details on the DN4 are provided in Section 2 and 3 of the manual). If you suspect the pain has a neuropathic component but the DN4 score is low (0-2) or the PainDETECT score is low (≤12), please still consider referral to GP/pain services as per the STAR pathway.

Identify the pattern of pain most commonly affecting the patient, ticking more than one box on the proforma when appropriate. If one pattern of pain dominates but another is present, please document the main pain type using the tick boxes and write a description of the other pain type(s) below.

Level of interference with daily life and function

Please ask how/whether the pain is limiting the patient's activity currently. Specify which activities they currently cannot perform or have extreme difficulty in doing because of their knee pain. Ask about associated symptoms such as giving way, 'catching', 'clunking', 'grinding' or instability. If patients report these symptoms, determine whether they are specifically associated with pain or in addition to more generalised pain. Ask about upon what leisure activities or hobbies this has impacted. Compare this to pre-surgery function and pre-arthritis function. Cross-reference these discussions and findings to the BPI interference score, which will also give an indication of level of interference.

Pain elsewhere and general pain history

Ask about and document any pain experience at any other sites in the body. This is particularly important as pain elsewhere is often associated with chronic pain after knee replacement.

Please list all pre-operative analgesia and current analgesia.

Please ask the following questions:

- If their knee didn't hurt now, would they take analgesia for any other pains?
- Have they had surgery for any prior pain conditions?
- Have they had previous surgery which resulted in a painful outcome?
- Do they have back and/or hip pain?
- Have they previously attended or been referred to pain services?
- Have they ever been diagnosed with or suffered from irritable bowel syndrome, migraine/frequent severe headache, tinnitus, fibromyalgia or chronic fatigue syndrome?

Multiple other pain problems suggest a generalized pain disorder as a component of their pain. In the context of other findings, consider involvement of pain services earlier than you might otherwise consider.

Expectations of surgery and related satisfaction

Expectations and satisfaction following surgery often go hand-in-hand but are distinctly different so try to ask specifically about both.

Please ask how they feel their knee is currently, and whether that is in line with their expectations prior to surgery (expectations about how they thought they would recover). Record whether their expectations were met, unmet or whether they are unsure. Go on to ask what it was they expected prior to surgery in terms of pain relief. What was the main influence in developing these expectations – was it the surgeon, pre-op education, GP, family or friends, internet? If expectations were unrealistic, it may be appropriate to provide some information on outcomes and recovery after knee replacement. If you feel the patient

would benefit from further explanation from their surgeon, consider referral for further discussion, education and explanation.

Also ask if they are satisfied with their outcome and progress following their knee replacement. If they are not satisfied, ask why. It is important in the context of dissatisfaction to explain that many patients continue to improve and become more satisfied over the first year or two following knee replacement surgery and that the motive behind this care pathway is earlier identification, assessment and management of problems which affect satisfaction.

ASSESSMENT PROFORMA SECTION 2: COMPLETION OF PAIN MEASURES

The patient will bring a completed assessment questionnaire booklet to the appointment. If they do not, then please ask them to complete the assessment questionnaire during the appointment (you will be provided with spare copies of the assessment questionnaire). This booklet includes validated questionnaires which assess pain severity and interference, neuropathic pain and depression and anxiety. The researcher will review and score each of these questionnaires and record the scores on the assessment proforma. However, if they have not had the opportunity to do this before the appointment starts, guidance on scoring the questionnaires is provided in the following section. Further information and guidance for each questionnaire is provided below.

Part 1: Pain severity and interference (Brief Pain Inventory)

The Brief Pain Inventory (BPI) is a widely used measurement tool for assessing clinical pain. The BPI allows patients to rate the severity of their pain and the degree to which their pain interferes with common dimensions of feeling and function. Initially developed to assess pain related to cancer, the BPI has been shown to be an appropriate measure for pain caused by a wide range of clinical conditions.

The BPI pain severity score is calculated by adding up the responses to the 4 questions and dividing the total by 4 to get a score from 0-10 (no pain to worst pain).

The BPI pain interference score is calculated by adding up the responses to the 7 questions and dividing the total by 7 to get a score from 0-10 (no interference to complete interference).

These scores can provide useful information to inform decisions regarding treatment.

Part 2: Neuropathic pain (PainDETECT)

The International Association for the Study of Pain (IASP) definition of neuropathic pain is 'pain caused by a lesion or disease of the somatosensory nervous system'. Neuropathic pain is a clinical description (and not a diagnosis) which requires a demonstrable lesion or a disease that satisfies established neurological diagnostic criteria. The term lesion is commonly used when diagnostic investigations (e.g. imaging, neurophysiology, biopsies, lab tests) reveal an abnormality or when there was obvious trauma. The term disease is commonly used when the underlying cause of the lesion is known (e.g. stroke, vasculitis, diabetes mellitus, genetic abnormality). Somatosensory refers to information about the body per se including visceral organs, rather than information about the external world (e.g., vision, hearing, or olfaction). The presence of symptoms or signs (e.g., touch-evoked pain) alone does not justify the use of the term neuropathic. Some disease entities, such as trigeminal neuralgia, are currently defined by their clinical presentation rather than by objective diagnostic testing. Other diagnoses such as postherpetic neuralgia are normally based upon the history. It is common when investigating neuropathic pain that diagnostic testing may yield inconclusive or even inconsistent data. In such instances, clinical judgment is required to reduce the totality of findings in a patient into one putative diagnosis or concise group of diagnoses.

We have included two neuropathic pain questionnaires in the assessment questionnaire, the PainDETECT and the DN4. This is because we do not know which one is most appropriate to use with patients who have long-term pain after knee replacement. If a patient meets the criteria for neuropathic pain on either questionnaire, please refer as appropriate.

The PainDETECT is a screening questionnaire for neuropathic pain. It consists of 9 questions and produces a total score from -1 to 38. A score of 12 or less indicates that a neuropathic

pain component is unlikely, a score of 13-18 indicates that the results are ambiguous however a neuropathic pain component could be present, and a score of 19-38 indicates that a neuropathic pain component is likely. Patients with a possible or probable neuropathic pain component should be referred to the GP to initiate neuropathic pain medications. If patients are already on neuropathic pain medications, then liaise with GP to: trial an alternative, increase the dose of pain medication, or refer to pain clinic for additional assessment and management. If the PainDETECT score indicates neuropathic pain but the DN4 score does not, please still consider referral.

Part 3: Neuropathic pain (Douleur Neuropathique 4)

The DN4 is a screening questionnaire for neuropathic pain. It consists of 7 questions, each of which has a 'yes' or 'no' response option. To score the questionnaire, add up the score for the 7 items (Yes=1, No=0). A score of 3 or more indicates a neuropathic pain component and the patient should be referred to their GP to initiate neuropathic pain medications. If the patient is already on neuropathic pain medications, then liaise with their GP to trial alternatives or increase the dose of pain medication, or refer to pain clinic for additional assessment and management. Please remember to refer to the 'pain pattern' section which should have given an indication of symptoms consistent with a neuropathic pain component. If the DN4 score indicates neuropathic pain but the PaindDETECT score does not, please still consider referral.

Part 4: Depression and Anxiety (Hospital Anxiety and Depression Scale)

The HADS is a validated questionnaire developed to identify depression and anxiety in non-psychiatric patients. It contains a depression subscale (7 questions) and an anxiety subscale (7 items).

To score the depression subscale, add up the responses to the 7 green questions on the assessment questionnaire (items 2,4,6,8,10,12,14) to get a total score ranging from 0-21. To score the anxiety subscale, add up the responses to the 7 blue questions on the assessment questionnaire (items 1,3,5,7,9,11,13).

A score of 8-10 suggests possible depression/anxiety and referral to the GP should be considered in the context of other factors. A score of 11 or above indicates probable

depression/ anxiety and patients should be referred to their GP. If medication has been started recently by their GP, it is reasonable to expect this to take some time to have an impact on their symptoms and subsequent score. If, however, they have been on long-term treatment and continue to score highly, it would be appropriate to highlight this to their GP to consider modification or alteration of their treatment regime. Please remember the HADs score is only a guide and not formally diagnostic. It gives an indication towards a high level of distress which may suggest anxiety and depression and this should be further assessed by an appropriate clinician i.e. GP. If the score is borderline (8-10) or even lower, but concerns exist after further questioning that there may be a need for further assessment to exclude anxiety or depression, then please refer to appropriate services. Please ensure you take into consideration interference ratings on the Brief Pain Inventory, social circumstances and that both lack of social support or present but negative/unhelpful support can make it harder to cope with borderline depression/anxiety and a lower threshold for referral may be appropriate.

ASSESSMENT PROFORMA SECTION 3: CLINICAL EXAMINATION

How to do the clinical examination – Posture

For the clinical examination, it is important to initially see the patient standing with both knees exposed, but in a way that does not make the patient uncomfortable or embarrassed.

Assessment of walking

The patient can use walking aids as required. A brief assessment of the patient walking should be performed to note any particular abnormal gait and the need for walking aids.

Clinical examination in lying position

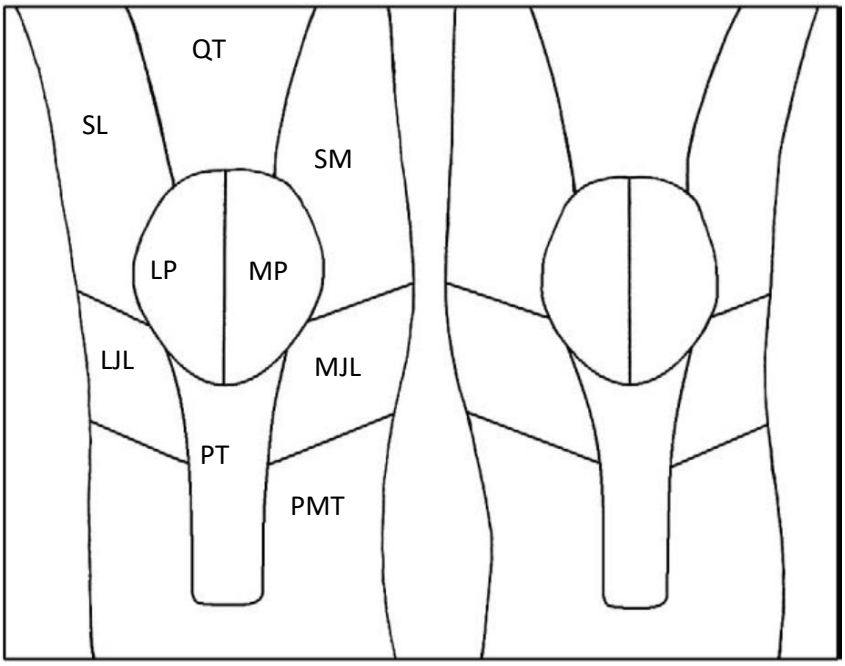
They should then be made comfortable on an examination couch, lying as flat as they can tolerate with a pillow behind their head.

ASSESSMENT PROFORMA SECTION 3.1: KNEE PALPATION TENDERNESS

Ask the patient to pinpoint where they are most tender around their knee. Initially perform gentle light palpation at various sites around the knee to get an impression of any generalised hypersensitivity or hyperaesthesia.

If acceptable and tolerable to the patient, next lightly rub the skin overlying the knee in different places and ask if this is painful, unpleasant or bothersome in any way. This can be compared to the other knee and if present is an indication of allodynia. If present, please record the area of allodynia on the knee map on the assessment proforma.

Specifically palpate the knee in a systematic manner for tenderness, leaving the areas that the patient reports as most tender until last. Specifically palpate medial joint line (MJL), medial patella (MP), lateral joint line (LJL), lateral patella (LP), quads tendon (QT), patella tendon (PT), superolateral (SL) and superomedial (SM) knee, and proximal medial tibia (PMT). These areas are demonstrated on the diagram overleaf. Document any sites of tenderness with single or multiple crosses on the map. Be sure to differentiate joint line pain from peripatellar pain and from proximal tibial tenderness.



Global tenderness is strongly suggestive of a non-surgical origin for pain. Focal tenderness may indicate a surgical issue and should be correlated with other signs and symptoms. Hyperasthesia or allodynia may be suggestive of a neuropathic component of the pain and should be considered in conjunction with history and scores. It may also be an indication of Complex Regional Pain Syndrome (CRPS) and should be considered as part of the CRPS assessment.

ASSESSMENT PROFORMA SECTION 3.2: WOUND INFECTION

Specific considerations that should be assessed and recorded on the assessment proforma are:

- **Wound** – is the wound fully healed or are there any areas of the wound that are still open or cause concern? This could include ooze (clear or purulent), redness around the scar area, residual scab, a retained stitch, dehiscence (sides of wound opened), ulceration, bleeding, inflammation, hypertrophy?
- **Skin temperature** – Put the backs of both hands on the non-operated knee first to gauge/feel the skin temperature. Then put the backs of your hands to feel the operated knee. Are they the same temperature? If no, is the operated knee hotter or cooler than the opposite knee?
- **Symptoms –** ask specifically about symptoms of fever, rigors, sweats, change in appetite, fatigue and generalised malaise. Remember that it is not uncommon after knee replacement for patients to have symptoms of generalised fatigue. Try to differentiate this from more specific symptoms which would raise suspicion of possible infection. Also ask if the patient has been prescribed antibiotics for a wound infection (or any other infection after surgery).

All patients require blood tests for C-Reactive Protein (CRP) as part of the assessment, and the results should be obtained in a timely manner and acted upon. The researcher should check the results of the CRP and the ESP should be notified as soon as possible of any elevated CRP results.

Remember that a CRP is sensitive but not specific for infection. It may be elevated for other reasons. In the context of an elevated CRP, history and other clinical signs are important. If there is any clinical suspicion for infection PLUS an elevated CRP level, refer to a surgeon. If there is minimal clinical suspicion but the CRP is raised then the blood test should be repeated approximately one month later. Please inform the research nurse and they will book the patient into an available STAR clinic slot. In this situation it is also important to explain to the patient that if their knee becomes red, hot, swollen and painful to move then

this is highly suggestive of infection and they should present to their GP or surgeon promptly.

ASSESSMENT PROFORMA SECTION 3.3: KNEE STIFFNESS/RANGE OF MOVEMENT

Assess first for ability to perform a straight leg raise to give a guide to extensor mechanism and quadriceps function, noting particularly an extensor lag and quads muscle tremor. If this is not possible due to pain or muscle weakness, assess for active extension of a flexed knee against gravity sat with the leg over the side of the couch. Whilst performing this test observe for evidence of an extensor lag, seen as a delay between quads contraction and lower leg extension.

An assessment of passive range of movement should be made with a goniometer. Assess for whether or not the patient can achieve full extension (recorded as 0^o), whether they have any hyperextension (recorded as negative extension i.e. a negative from zero). Then assess full passive flexion e.g. a patient who has ROM from 5-90^o would be recorded as 5^o extension, 90^o flexion. A patient who has 5^o hyperextension and 90^o flexion would be recorded as -5 to 90^o.

Extension deficit (fixed flexion deformity) greater than 10^o, excessive hyperextension greater than 10^o or flexion less than 85^o is sufficient for surgeon referral. Lack of active extension or a gross extensor lag may suggest a significant extensor mechanism problem, which would warrant a surgeon referral. Range of movement deficit should where possible be considered with reference to pre-operative range of movement which should be available from clinic/operation notes.

Passive flexion

Extension and hyperextension

ASSESSMENT PROFORMA SECTION 3.4: INSTABILITY

Assessment needs to be made of knee stability in the anterior/posterior direction and varus/valgus direction. This should be done with the patient lying supine on an examination couch with a single pillow under their head.

A posterior draw test should be performed. The knee is flexed as close to 90^{o} as the patient can tolerate. Every effort should be made to ensure the patient relaxes their hamstrings. Both hands are placed around the proximal tibia and a posterior force is applied to the proximal tibia. Please note that in posterior-stabilised knees, this will reproduce a solid 'clunk' and this is normal. In posterior cruciate retaining knees, an attempt should be made to grade any instability present. If an unreplaced normal contralateral knee is available, then comparison with the other side is the most useful guide. When not available, amount of posterior translation should be assessed and estimated. If positive, grade 1+/2+/3+ (5mm/10mm/15mm).

Varus/valgus stability should be assessed by supporting the knee and holding it flexed at approximately 30^{o}. To assess varus stability, one hand should be placed on the medial aspect of the knee with the other around the lateral aspect of the ankle. The knee should be stressed in a varus direction to determine degree of opening. The degree of opening should be assessed and estimated. If positive, grade 1+/2+/3+ (5mm/10mm/15mm). Again if available, this should be compared to the contralateral normal unreplaced knee. Valgus stability should be assessed in the same way but with a hand on the lateral knee and medial ankle. Please note when assessing for varus/valgus stability that care must be taken to ensure that hip rotation does not confuse assessment. An alternative technique for the larger leg is to anchor the ankle underneath the examiner's arm and support the knee with both hands.

If 2+ or greater instability in any direction is present, this is sufficient for surgeon referral.

Posterior draw

Valgus stability

Varus stability

ASSESSMENT PROFORMA SECTION 3.5: PATELLOFEMORAL JOINT

An assessment should be made of patellofemoral tracking through range of flexion and extension. Any concern for patellar maltracking or subluxation should prompt surgeon referral. Peripatellar tenderness on palpation should give an indication of potential patellofemoral joint concerns. Patellofemoral crepitus may be felt in an unresurfaced patella. Patellofemoral compression test is a sensitive test; however, caution is needed when performing this, as it can elicit pain. An appreciation for the degree of pain hypersensitivity and also the likelihood for patellofemoral problems should be taken into account from the history and examination findings so far to guide likely patient response. A gentle and cautious approach should be adopted initially to minimise the potential for severe discomfort. Thumbs should be applied to the anterior patella and it should be gently compressed towards the trochlea groove. Any initial pain on this pressure is not a positive test and is likely to be due to overlying skin sensitivity. Whilst pressure is being applied, the

patient is asked to carefully contract their quadriceps muscles. A positive test is discomfort elicited on quads contraction.

If the test is strongly positive, then consider referral to surgeon for assessment of patellofemoral problems.

ASSESSMENT PROFORMA SECTION 3.6: COMPLEX REGIONAL PAIN SYNDROME

Complex regional pain syndrome (CRPS) is a condition in which a person experiences persistent severe and debilitating pain. Although most cases of CRPS are triggered by an injury, the resulting pain is much more severe and long-lasting than normal. The pain is usually confined to one limb, but it can sometimes spread to other parts of the body. The skin of the affected body part can become so sensitive that just a slight touch, bump or even a change in temperature can provoke intense pain. Affected areas can also become swollen, stiff or undergo fluctuating changes in colour or temperature. Many cases of CRPS gradually improve to some degree over time, or get completely better. However, some cases of CRPS never go away, and the affected person will experience pain for many years.

History and examination findings prior to this stage of assessment will inform the possibility of a diagnosis of CRPS. A combination of both signs and symptoms are required for formal diagnosis. High pain severity unexplained by other findings and diffuse pain, often neuropathic in nature, which may radiate away from the joint are important factors in the history which should be considered. On examination, evidence of hyperaesthesia or allodynia should be assessed. An indication of either may well have been identified during general palpation testing. A positive finding would be indicated by a patient experiencing pain, discomfort or distress associated with light palpation anywhere over the knee or from gentle brushing of the hand across the knee. Such palpation should be performed in a systematic manner and where uncertainty is present findings should be compared to a normal, unreplaced contralateral knee where available or another area of pain-free unoperated skin.

Swelling of the limb in the context of a CRPS diagnosis is likely to be different to expected post-operative swelling and tends to be more diffuse often with associated hyperaemic and shiny skin and not confined to a persistent intraarticular effusion.

Colour changes may be a patient-reported symptom or a clinical sign and may vary to include excessively pale, excessively red or poor perfusion and a blue/grey discolouration. Skin colour should be compared to the contralateral limb. Any patches of abnormal hair growth (thicker and darker or sparse compared to the contralateral side) should also be noted and may represent a further positive sign.

If any of the above signs or symptoms are present, this should be sufficient to raise suspicion of a potential CRPS diagnosis and formal criteria should be assessed. The formal CRPS criteria checklist is provided in Appendix 5.

For the formal diagnosis of CRPS to be made, a patient must satisfy three or more symptoms or two or more signs. If CRPS is suspected but the formal criteria are not met, please refer the patient to their GP to begin neuropathic pain medications medications, and recommend referral onto pain clinic if minimal or no response to analgesia. If formal CRPS criteria are met, refer the patient to the pain services via their GP. Physiotherapy should be continued in either of the above scenarios, so as to encourage normal use and touch of the limb, and improvement in function despite the limitations of pain.

ASSESSMENT PROFORMA SECTION 4: RADIOGRAPHS

Practicalities

Please ensure that patients are x-rayed before attending the clinic appointment. For radiographic assessment a patient requires an AP weight-bearing long-leg alignment film, a true lateral and a patella skyline. It is important to ensure on the long-leg film that the patella is situated centrally on the distal femur, indicating that it is not a rotated film. Rotation of the radiograph will give inaccurate alignment measurements. To minimise the chance of a rotated film, please use the following standardised wording when ordering the x-ray:

> 'Post-op [left/right] TKR. Persistent pain. Weight-bearing, long-leg alignment film. Please ensure limb is in neutral rotation with patella pointing directly forward to allow accurate alignment assessment. Happy to accept any malrotation caused at hip and ankle in order to achieve true AP long leg of the knee'.

If the film is rotated, continue with the clinic appointment and do all the assessments except malalignment. At the end of the clinic ask the patient to have another x-ray taken and let them know that you will telephone them if the radiograph highlights any problems. Please ensure that you then review the radiograph and complete the assessment proforma as soon as possible. In addition, a fixed flexion deformity of the knee will prevent a useful AP long leg radiograph from being taken. If the knee appears very flexed or clinical assessment has found, a marked fixed flexion deformity no accurate assessment of coronal alignment can be made and should be excluded. Please record this on the assessment proforma.

Assessment

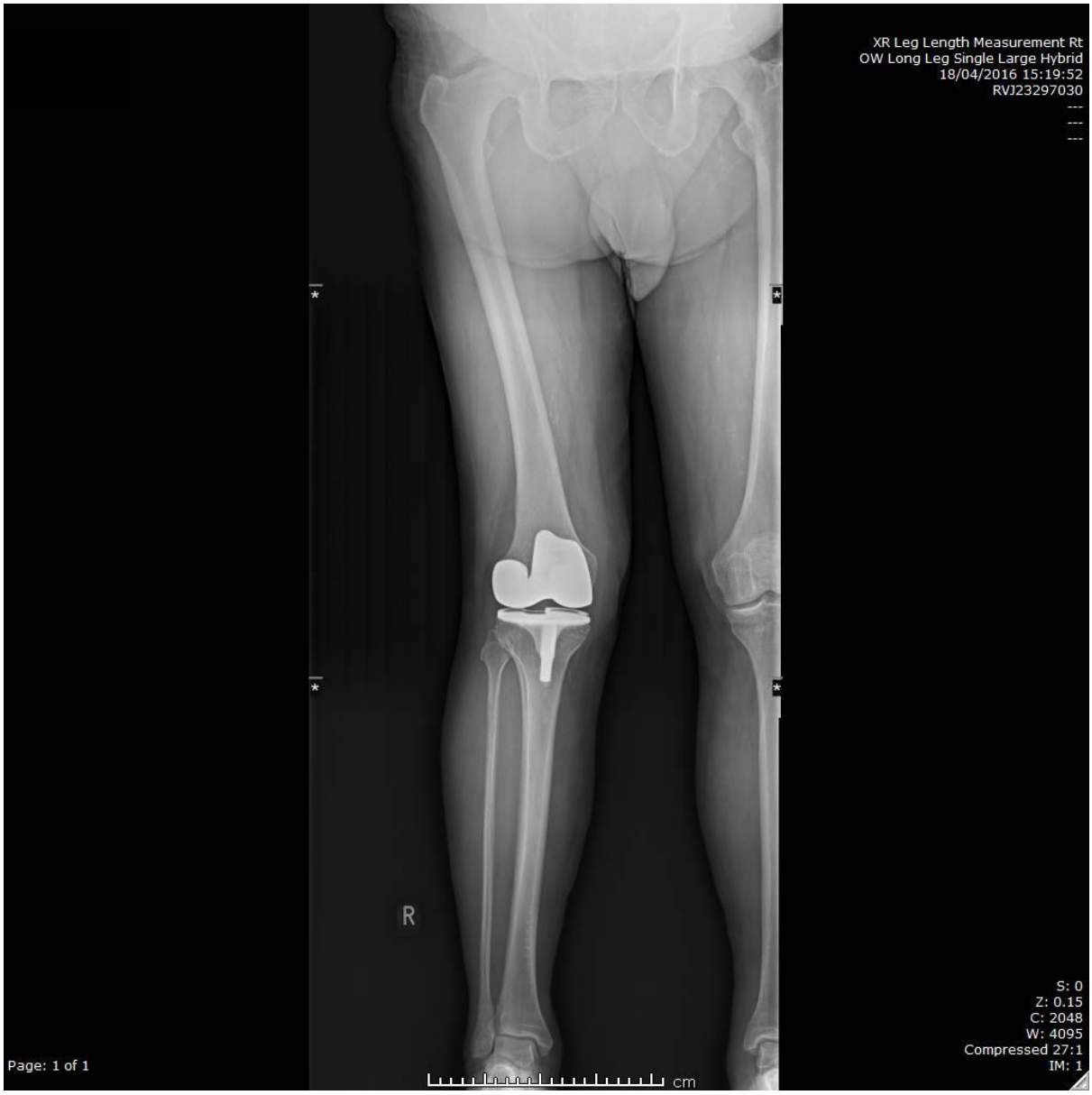
Coronal alignment should be assessed by measuring the hip-knee angle on the long-leg film. This should be done by measuring an angle from the centre of the femoral head to the distal centre of the femoral knee prosthesis and on from here to the centre of the ankle. A 0^{o} alignment indicates a neutrally aligned knee. Any deviation from neutral should be recorded in number of degrees varus or valgus.

Other factors to consider on radiograph:

- **Fracture** – follow the cortices around the proximal tibia, distal femur and patella, particularly around the tip of the tibial prosthesis and the anterior flange of the femur to ensure there is no evidence of a breach in the cortex indicating an undisplaced fracture.
- **Sizing** – assess the tibial component size in comparison to the underlying tibial bone: does it match? Is there overhanging prosthesis, is it grossly undersized? Assess the femoral component, particularly on the lateral view to see whether the posterior prosthesis lines up with the native posterior cortex, suggesting restoration of posterior condylar offset.
- **Fixation** – in cemented prostheses, is there an even cement mantle visible or are there clear defects? Are there any gaps between prosthesis and bone suggesting insufficient fixation?
- **Position** – despite overall alignment, are there any concerns of gross component malposition? Look for marked flexion or extension of femoral prosthesis, reverse tibial slope or excessive tibial slope of the tibial prosthesis.

If there is any gross concern regarding alignment, fracture, sizing, fixation or position of implants, then please consider to referral to surgeon. If there is any uncertainty or concern at all regarding any radiograph, then the Principal Investigator in each centre is available for review and discussion of any radiographs.

Example of a well centred long leg radiograph with the patella pointing forwards. Lines are drawn showing technique for measuring hip-knee angle



Example of an inadequate rotated long leg radiograph showing a rotated prosthesis and an off-centre patella

Example of a radiograph that shows cause for concern with a fracture to the patella

Example of a radiograph showing cause for concern with a tilted tibial component with a fracture at the tip of the stem

ASSESSMENT PROFORMA SECTION 5: DECISIONS ABOUT REFERRAL AND/OR FOLLOW-UP

The assessment proforma and guidance in this manual are intended to provide a framework to assist with assessment and referral of patients with pain after knee replacement. If you have any concerns regarding an individual patient that you feel warrant onward referral to any provider, then please do not hesitate to do so, even if criteria are not fully met. At each trial centre there is a designated orthopaedic surgeon who should serve as a point of contact for advice and further clarification on any matters of concern or uncertainty regarding the clinical care of patients. Copies of all referral letters should be sent to the local researcher, the patient and the treating orthopaedic surgeon. A standardised template for STAR clinic referral will be provided giving basic background to the study, as well as a template of clinic outcome which will require a brief summary of clinical findings and suggestions for the onward referrer to be added.

It is important to note that not all patients with pain will meet criteria for, or indeed will need, onward referral. A proportion of patients will have pain that will simply improve with time and it is entirely appropriate that such patients are simply followed up to monitor progress. If necessary, referrals can be made at a later date after telephone follow-up consultations. All patients who are being monitored without referral should have a telephone follow-up consultation 6 weeks after the clinic, 3 months after the clinic and 6 months after the clinic. At telephone consultation, if a patient's pain is improving/improved, then one further follow-up consultation should be scheduled to ensure that this is sustained. If pain persists however, a minimum of 3 telephone consultations should be conducted as per above schedule. The 6 month post clinic telephone consultation should tie in with the trial follow-up questionnaire which includes the Brief Pain Inventory and the Oxford Knee score. If questionnaire responses and consultation findings confirm persistent symptoms of concern, this should prompt a dual referral to the orthopaedic surgeon (to check for subtle surgical problems) and to a pain specialist via the GP.

ASSESSMENT PROFORMA SECTION 6: TELEPHONE FOLLOW-UP

At the end of the assessment proforma, you are asked to write a date that you will conduct a follow-up telephone call with the patient. This is covered in detail in Part 2 of the manual.

SAFETY REPORTING

All adverse reactions that are directly attributable to the intervention should be reported to a member of the research team, who will then work with you to complete an adverse reaction form.

Adverse reactions are defined as any untoward medical occurrence or effect in a clinical study participant which is directly related to the trial intervention. To meet the criteria to be reported as an adverse reaction, the occurrence needs to have a causal relationship with the trial intervention.

A serious adverse reaction is defined as any untoward medical occurrence or effect which is directly attributable to the trial intervention and meets any of the following conditions:

- Results in death
- Is life-threatening
- Requires inpatient hospitalization (overnight stay) or prolongation of existing hospitalisation
- Results in persistent or significant disability / incapacity
- Is a congenital anomaly / birth defect
- Is otherwise considered medically significant by the investigator

PART 2: TELEPHONE FOLLOW-UP CALLS

TELEPHONE FOLLOW-UP PROCEDURES

At the end of the assessment proforma, you are asked to write a date that you will conduct a follow-up telephone call with the patient. All patients who attend a clinic appointment will have at least one and up to a maximum of 6 follow-up telephone consultations to allow for monitoring of patients over the 12 month follow-up period of the trial. This is to follow-up on the care that patients are receiving and to ensure that any referrals are being undertaken. Additionally, further referrals can be made on the basis of these telephone follow-up consultations. These phone calls can be conducted during the clinic if you have time or at another time during the week.

A copy of the telephone proforma is provided in Appendix 6. At the beginning of each assessment clinic, a member of the research team will provide you with a 'telephone proforma for intervention follow-up' for any patients who require a follow-up telephone call that week. On this proforma you will be provided with information about patient name, contact details, date of surgery, date they attended an assessment clinic appointment and a summary of the clinic outcome and treatment to date.

Details of each telephone call should be recorded on the 'telephone proforma for intervention follow-up'. During the telephone call you will need to ask the patient if they have received the treatment they were referred to. If any referrals that you requested have not been conducted, you may need to follow-up on these. If you think the patient requires further referrals based on this telephone discussion, then these can be made and should be recorded on the telephone proforma.

Completed telephone proformas should be given to a member of the research team.

If there is time during the clinic when you are not seeing patients, then this clinic time can be used to conduct telephone follow-up calls to participants. The researcher will bring the relevant forms to you at the beginning of the clinic.

APPENDIX 1: PATIENT INFORMATION LEAFLET

Insert local NHS trust logo here

Star
Support and treatment after joint replacement

Evaluation of a care pathway for patients with long-term pain after knee replacement

(IRAS Project ID: 20489)

Helping you decide whether or not to join our research project

We would like to invite you to take part in our research project. Before you decide to take part it is important for you to understand why the research is being done and what it will involve. Please read the following information to help you to decide whether or not you wish to take part. You may wish to discuss this with family, friends or your GP.

If there is anything you do not understand, or if you would like further information, please contact [insert name of local researcher] on [insert number]

Part 1 tells you the purpose of the project and what will happen if you take part.

Part 2 gives you more detailed information about how the project will happen.

Part 1

1. What is the purpose of the STAR project?

- Around one in five people who have a knee replacement find that they have pain in the months afterwards. We believe that the care that is provided to people with this kind of pain could be improved.
- The purpose of the STAR project is to find out if a care pathway is helpful for people with long-term pain after knee replacement. A care pathway is a way of trying to make sure that patients get the right care at the right time. The STAR care pathway involves a single clinic appointment with a healthcare professional and onwards referral to other services if appropriate.
- We have made a short video about the STAR project, and how patients have helped us to design this project. This is available on YouTube at: https://goo.gl/52HxLO
- As we do not yet know whether the STAR care pathway will help people or not, we need a research project. The research compares people who have the STAR care pathway with people who have usual NHS care, so that we can find out which is best.

2. Do I have to take part?

- No. It is up to you to decide whether or not to take part in the STAR project and taking part is voluntary. You do not have to give a reason for deciding not to take part. Your decision will not affect, in any way, the standard of treatment you are receiving or any treatment you may have in the future.

3. Why have I been invited to take part?

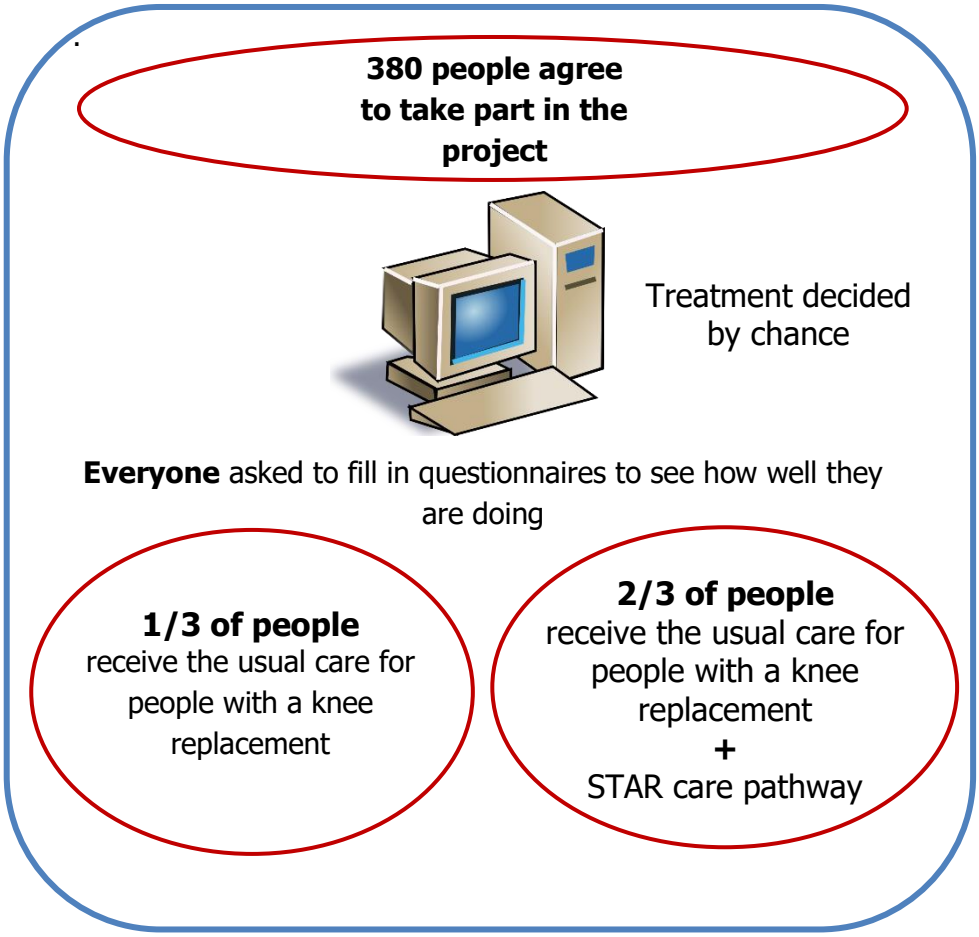
- We are approaching you about the project because you kindly completed the STAR questionnaire that we sent you about your recent knee replacement. In this questionnaire, you told us that you experience pain in your replaced knee.

4. What will happen to me if I take part?

- If you decide you would like to take part in the study after you have read all the information about the project and had a chance to talk to a researcher, you will be asked to provide your written agreement to doing so, which we call your ‘consent’.

- Everyone who takes part in the STAR project will receive their usual NHS care that they would normally receive at hospital and from their GP. Those people on the STAR care pathway will also attend one clinic appointment at hospital, and if appropriate they may then go on to receive other health services.

- We do not know whether the STAR care pathway will make a difference for people with pain. The best way of testing whether the STAR care pathway is better than usual NHS care is to compare people who have the care pathway with people who have usual NHS care. To do this, we will ask some people to try out the STAR care pathway and ask other people to continue with their usual NHS care. So that this is done fairly, a computer will choose who has the pathway and who has usual care. This is done by chance. Everyone in the project will still have the usual care that is provided by their hospital and GP. People not offered the STAR care pathway can still access medical care if they have ongoing problems with their knee replacement.
- We are asking 380 people with long-term pain after knee replacement to take part in the project; 1/3 of patients will receive their usual care only, and 2/3 will receive the STAR care pathway as well as their usual care. This means you will have a 2 in 3 chance of having the care pathway. More people will receive the STAR care pathway because we need more information on whether this treatment is better than usual care or not.



- We will ask everyone to complete questionnaires about their knee and their general health when they agree to take part in the project, and then again after 6 months and 12 months. Each of these questionnaires may take you

up to 40 minutes to complete. You can fill in the questionnaires at home. You will be offered the choice of doing this on paper or online. If you need any help filling in the questionnaires, a member of the research team can help you over the telephone or in person.

- You will be given diaries to record any health services that you may use over the course of the project. You will also be given folders to keep details of your prescribed medicines. These diaries and folders are for you to keep and refer to when you fill in the study questionnaires.

- With your agreement we will let your GP know that you are taking part in this project.

5. What is the STAR care pathway?

- This involves coming to the hospital for an appointment with a healthcare professional who will ask you questions about your pain and examine your knee. You will only need to do this once. They will also take a blood sample and may ask you to have X-rays taken of your knee and of your whole leg. Some of these may be extra to those that you would have if you did not take part. X-rays use ionising radiation to form images of your leg. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this project will add only a very small chance of this happening to you. We estimate the additional risk is approximately 1 in 1 million.
- If you need X-rays, you will be asked to have these done first. This may take an hour or more depending on the waiting times. The appointment with the healthcare professional will take up to an hour. The total appointment time may last up to 2 hours if you need to have X-rays of your knee. The appointment will help us to understand why you have pain in your replaced knee. We are sorry that we are unable to refund your travel expenses for attending this appointment.
- After this appointment you may be referred to other healthcare professionals. This may include an orthopaedic surgeon, physiotherapist, pain specialist or your GP. We may decide that for some people the most

appropriate course of action is for them to regularly monitor their pain, and then begin treatment if the pain does not get better or worsens.

- A healthcare professional will continue to monitor your care over the 12 month duration of the project, and will telephone you up to 6 times over this period to see how you are doing.

6. If my pain improves should I drop out of the study?

- If you start to feel better at any point during the study, we would like you to carry on with the research. This is so we can understand what helps people to improve.

7. What is usual NHS care?

- Everyone will still be able to continue with their usual NHS care. This can vary depending on where you live, but may involve seeing your surgeon for follow up appointments. Everyone in the project will still be able to access medical care as they normally would if they have problems with their knee replacement. If you see a healthcare professional, you can still carry on with the project. We will simply ask you about this in the study questionnaires.

8. What are the possible benefits and disadvantages of taking part?

- If you are offered the STAR care pathway, you will be invited to come to the hospital for an appointment which may last up to 2 hours. This may be longer if the waiting time for X-rays is more than an hour. You may also be asked to attend other hospital or GP appointments as part of the STAR care pathway. This will take up your time and we do not know if this kind of extra appointment will be helpful to you. We are sorry that we are not able to refund your travel costs for attending these appointments.
- If you are chosen for either the STAR care pathway or for usual NHS care, a possible disadvantage is the time it takes you to complete the questionnaires. This may be up to 40 minutes for each questionnaire booklet.
- Although this research project may not benefit you directly, we hope it will help people undergoing knee replacement in the future.

This completes Part 1 of the Information Booklet.
If the information in Part 1 has interested you and you are considering taking part please continue to read the additional information in Part 2 before making any decisions.

Part 2

9. Is the project confidential?

- Yes, all the information you give us (we refer to this as 'data') will be kept strictly confidential. We keep a record of your name and address for one year after the end of the project so that we can contact you if needed. The data will be stored in locked filing cabinets and on password-protected computers and will only be accessed by members of the research team. Your name will not be included in any research publications and we will not tell anyone outside the research or healthcare team your name.

10. What will happen if I don't want to carry on with the project?

- Your participation is voluntary and if you decide to take part you are still free to withdraw at any time, without giving a reason, and without your medical care or legal rights being affected. If you do decide not to continue with the project, or lose the ability to take part during the course of the project, we would keep and use any information you have given us up to that point, unless you tell us that you would like your information removed from the project.

11. What will happen to the results of the project?

- You will be provided with a brief report of the findings of this research project once the project has finished, if you so wish. A summary will also be placed on the University of Bristol's website.
- The results of this project will be published in reports, scientific journals and presented at conferences to healthcare professionals, health policy makers, researchers and other patients.
- After the end of the project, we would like to keep the information you have given us to support other research in the future, and share this with other researchers. We will ask your permission to do this on the consent form. If we do share your information, we will not include any names or anything that might mean that people could identify you.

12. Who is organising and funding this study?

- The project is being carried out by researchers from universities and NHS hospitals across the UK, one of which is [INSERT HOSPITAL NAME]. The project is sponsored by North Bristol NHS Trust and funded by a grant from the National Institute for Health Research, which is funded by the Department of Health.

13. How to ask for advice or make a complaint

- For general advice about research please contact:
[insert local R&I contact details]
- If you wish to make a formal complaint please contact:
[insert contact details for local Advice & Complaints Team]

14. What happens if something goes wrong?

- If there is negligent harm during the study when the NHS body owes a duty of care to the person harmed, NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the study. NHS indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm.

15. Who has reviewed the project?

- This project has been given a favourable opinion for conduct in the NHS by the National Research Ethics Service Committee [insert COMMITTEE NAME HERE].

16. What happens next?

- A researcher will telephone you soon to answer any questions you may have and see if you would like to meet with them to discuss the STAR project in more detail. If you do, they will arrange to come and discuss the study further with you at a convenient time either at your home or the hospital. If you would like to contact us before this for any reason, please phone [name of local researcher] on [telephone number].

Thank you very much for taking the time to read this information leaflet.
Please keep this copy of the information leaflet.

If there is anything you don't understand or if you would like more information, please contact:

[Insert local researcher name, phone number and email here]

STAR is an independent research programme funded the National Institute for Health Research (NIHR) Programme Grants for Applied Research Programme. The views expressed in this information leaflet are those of the STAR team and not necessarily those of the NHS, the NIHR or the Department of Health.

APPENDIX 2: ASSESSMENT PROFORMA

Star
Support and treatment after joint replacement

Proforma for STAR assessment clinics

To be completed by a health professional during a clinic appointment with a patient. Please refer to the training manual for further advice and guidance on completing this form.

Your name:	Your job title:	Your Band:
Date of clinic: _ _ /_ _/_ _ _ _	Appointment start time: _ _:_ _ am/pm	Appointment end time: _ _:_ _ am/pm
Was an x-ray conducted? Yes ☐ No ☐	Time patient went for x-ray: _ _:_ _ am/pm	Time patient returned from x-ray: _ _:_ _ am/pm
Patient name:	Patient mode of transport to appointment:	Patient travel time: _ _ _ _minutes
Did the patient take time off work for the appointment?: Yes ☐ No ☐		
Was the patient paid for this time taken off work?: Yes ☐ No ☐		

1. Pain report

General history and information

Pain compared to pre surgery

Better ☐ Worse ☐ Unsure ☐

Pain pattern

Night pain ☐ Day pain ☐ Unpredictable ☐ Pain on walking ☐

Pain on standing ☐ Pain at rest ☐

Level of interference of pain with daily life and function

Pain elsewhere and general pain history

List of other pain problems

Multiple other pain problems suggest a generalized pain disorder as a component of their pain. In the context of other findings, consider involvement of pain services.

Expectations of surgery and related satisfaction

Met ☐ Unmet ☐ Unsure ☐

2. Completion of pain measures

Please refer to the assessment questionnaire which the patient will bring with them to the consultation. Please write the questionnaire scores and any discussion with the patient in the boxes below.

Part 1: Pain severity and pain interference (BPI)

Pain severity score: ☐☐

Pain interference score: ☐☐

Scoring instructions:

Page 2: Add up the responses to the 4 questions and divide by 4 to get a score from 0-10 (no pain to worst pain)

Page 3: Add up the responses to the 7 questions and divide by 7 to get a score from 0-10 (no interference to complete interference)

Part 2: Neuropathic pain (PainDETECT)

Score: ☐☐

Scoring instructions:

Page 4-5: Add up the responses to the 9 questions to get a total score from -1 to 38.

A score of 13-18 indicates that the results are ambiguous; however a neuropathic pain component could be present. A score of 19-38 indicates that a neuropathic pain component is likely. Patients with a possible or probable neuropathic pain component should be referred to the GP to initiate neuropathic pain medications. If patients are already on neuropathic pain medications, then liaise with GP to trial alternative or increase the dose of pain medication or refer to pain clinic for additional assessment and management.

Part 3: Neuropathic pain (DN4)

Score: ☐☐

Scoring instructions:

Page 6: Add up the responses to the 7 questions (Yes=1, No=0).

A score of ≥3 indicates a neuropathic pain component and patients should be referred to the GP to initiate neuropathic pain medications. If patients are already on neuropathic pain medications, then liaise with GP to trial alternative or increase the dose of pain medication or refer to pain clinic for additional assessment and management.

Part 4: Depression and anxiety (HADs)

		Scoring instructions:
Depression score:	☐☐	Pages 7-8: Add up the responses to the 7 GREEN questions (2,4,6,8,10,12,14) to get a score from 0-21.
Anxiety score:	☐☐	Pages 7-8: Add up the responses to the 7 BLUE questions (1,3,5,7,9,11,13) to get a score from 0-21.

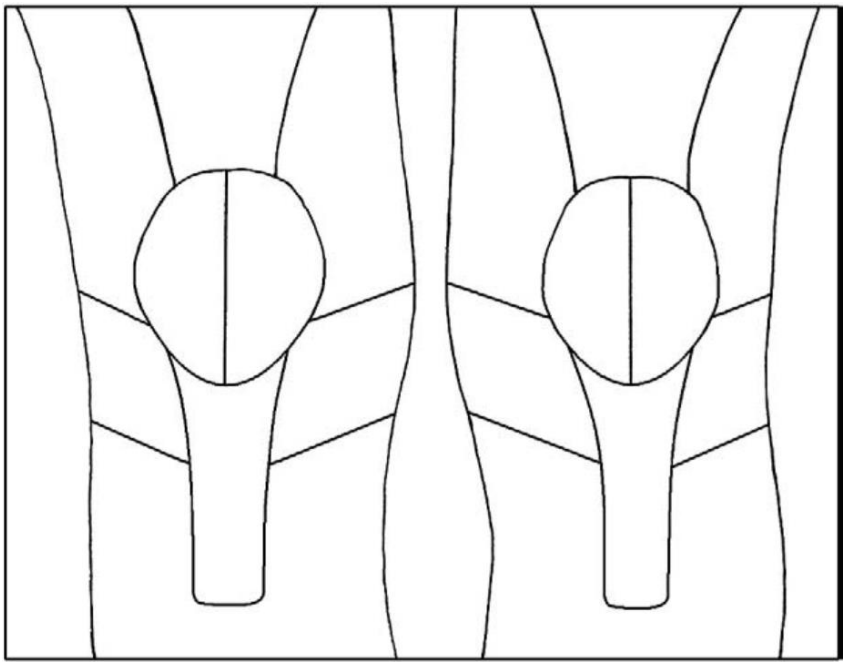
A score of 8-10 suggests possible depression/anxiety and referral to the GP should be considered in the context of other factors. A score of ≥11 indicates probable depression/ anxiety and patients should be referred to their GP

3. Examination

3.1) Knee palpation tenderness

Globally tender: Yes ☐ No ☐

Focally tender: Yes ☐ No ☐ If yes, please indicate where on the diagram



3.2) Wound infection

Wound concerns:	Yes ☐	No ☐
If yes what?	Ooze/Inflammation/Scab/Dehiscence	
Skin redness:	Yes ☐	No ☐
Increased skin temperature:	Yes ☐	No ☐
Other skin changes:	Yes ☐	No ☐
If yes what?		
Fever:	Yes ☐	No ☐
Rigors:	Yes ☐	No ☐
Sweats:	Yes ☐	No ☐
CRP elevated*:	Yes ☐	No ☐

*to be completed after blood test results received

If there are any clinical suspicion for infection PLUS an elevated CRP level, refer to a surgeon.

3.3) Stiffness/range of movement

Maximum passive extension: ☐☐

Maximum passive flexion: ☐☐☐

(Hyperextension to be recorded as negative extension)

Extension greater than 10 degrees or flexion less than 85 degrees sufficient for surgeon referral

Active extension:	Yes ☐	No ☐
Extension lag:	Yes ☐	No ☐

Lack of active extension or a gross extensor lag in conjunction with the lateral knee x-ray may suggest a significant extensor mechanism problem, which would warrant a surgeon referral

3.4) Instability

Sagittal: Posterior draw test at 90°: Positive ☐ Negative ☐

If positive, grade: 1+/2+/3+ (5mm/10mm/15mm)

Coronal: Varus stability test at 30°: Positive ☐ Negative ☐

If positive, grade: 1+/2+/3+ (5mm/10mm/15mm)

Valgus stability test at 30°: Positive ☐ Negative ☐

If positive, grade: 1+/2+/3+ (5mm/10mm/15mm)

If 2+ or greater instability in any direction, sufficient for surgeon referral

3.5) Patellofemoral joint

Patella compression test: Positive ☐ Negative ☐

(Patient report of pain when manual pressure is applied to the patella by the examiner's thumbs and the patient is asked to contract their quadriceps muscles (thigh muscle))

If the test is positive, then refer to a surgeon

3.6) Complex regional pain syndrome

Pain that is spreading/radiating away from joint:	Yes ☐	No ☐
Allodynia or touch sensitivity of the skin:	Yes ☐	No ☐
Swelling of the limb:	Yes ☐	No ☐
Colour changes/abnormal hair grown:	Yes ☐	No ☐
CRPS suspected:	Yes ☐	No ☐
Formal diagnostic criteria assessed:	Yes ☐	No ☐

If yes, outcome:

If CRPS is suspected but the formal criteria are not met, please refer the patient to their GP to begin neuropathic pain medications. If formal CRPS criteria are met, refer the patient to the pain services via their GP.

4. X-rays

Mechanical hip knee alignment on long leg x-ray

Neutral: Yes ☐ No ☐

Varus: Yes ☐ No ☐ Number of degrees: ___

Valgus: Yes ☐ No ☐ Number of degrees: ___

If alignment is greater than 5^{o} from neutral , then refer to surgeon

Any gross concern with sizing, alignment, position, fixation or fracture: Yes ☐ No ☐

If yes, please specify and refer patient as appropriate:

5. Decision about referral and/or follow-up

Based on the assessment, what referrals are you going to make? (tick all that apply):

Surgeon referral because of infection	
Surgeon referral because of malalignment	
Surgeon referral because of stiffness	
Surgeon referral because of patellofemoral joint problems	
Surgeon referral because of instability	
GP referral because of depression	
GP referral because of anxiety	
GP referral because of neuropathic pain	
Pain clinic referral because of CRPS (via GP)	
Referral to physiotherapy because of stiffness	
Referral to physiotherapy because of pain that has origins in hip or elsewhere	
Referral to physiotherapy for other reasons. Please state reason:	
Follow-up to monitor pain	
Other, please specify:	

6. Follow-up call

Date first follow-up telephone call due: ☐☐/☐☐/☐☐☐☐

APPENDIX 3: ASSESSMENT QUESTIONNAIRE

For office use only:

Study ID | | | | Initials | | | | DoB | | | | | 19 | | |

Assessment Questionnaire

Please complete this short questionnaire before you go into your appointment

Part 1: Your knee pain

The following questions ask about the pain you experience in your **replaced knee.**

1. Please rate your pain by circling the one number that best describes your pain at its **worst** in the last **24 hours**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

2. Please rate your pain by circling the one number that best describes your pain at its **least** in the last **24 hours**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

3. Please rate your pain by circling the one number that best describes your pain **on average**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes how much pain you have **right now**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

Circle the one number that describes how, during the past **24 hours**, pain has **interfered** with your:

7. General activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

8. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

9. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

10. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

11. Relationship with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

12. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

13. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Part 2: About how your pain feels

Please answer these questions about the pain you have experienced in your **replaced knee** over the **past 4 weeks**

1.) Do you suffer from a burning sensation (e.g. stinging nettles) in your replaced knee?

Never[0]	Hardly noticed[1]	Slightly[2]	Moderately[3]	Strongly[4]	Very strongly[5]

2.) Do you have a tingling or prickling sensation in the area of your replaced knee (like crawling ants or electric tingling?)

Never[0]	Hardly noticed[1]	Slightly[2]	Moderately[3]	Strongly[4]	Very strongly[5]

3.) Is light touching (clothing, a blanket) on your replaced knee painful?

Never[0]	Hardly noticed[1]	Slightly[2]	Moderately[3]	Strongly[4]	Very strongly[5]

4.) Do you have sudden pain attacks in your replaced knee, like electric shocks?

Never[0]	Hardly noticed[1]	Slightly[2]	Moderately[3]	Strongly[4]	Very strongly[5]

5.) Is cold or heat (bath water) on your replaced knee occasionally painful?

Never[0]	Hardly noticed[1]	Slightly[2]	Moderately[3]	Strongly[4]	Very strongly[5]

6.) Do you suffer from a sensation of numbness in your replaced knee?

Never[0]	Hardly noticed[1]	Slightly[2]	Moderately[3]	Strongly[4]	Very strongly[5]

7.) Does slight pressure on your replaced knee e.g. with a finger, trigger pain?

Never[0]	Hardly noticed[1]	Slightly[2]	Moderately[3]	Strongly[4]	Very strongly[5]

8.) Please circle the picture that best describes the course of your pain:

Persistent pain with slight fluctuations[0]

Persistent pain with pain attacks[-1]

Pain attacks without pain between them[1]

9.) Does your pain radiate to other regions of your body?

No[0] ……. ☐ Yes[2]…….☐

Part 3: About how your pain feels

These questions refer to the pain in your replaced knee.

Does the pain have one or more of the following characteristics?

		Yes	No
1 -	**Burning**		
2 -	**Painful cold**		
3 -	**Electric shocks**		

Is the pain associated with one or more of the following symptoms in the same area?

		Yes	No
4 -	**Tingling**		
5 -	**Pins and needles**		
6 -	**Numbness**		
7 -	**Itching**		

Part 4: About how you feel

It is well known that emotions play an important part in most illnesses. Please read each item and place a tick in the box that comes closest to how you have been feeling in the **PAST WEEK.** Please tick (✓) one box only.

1. I feel tense or 'wound up':

Most of the time[3]	A lot of time[2]	Time to time, occasionally[1]	Not at all[0]

2. I still enjoy the things I used to enjoy:

Definitely as much[0]	Not quite so much[1]	Only a little[2]	Hardly at all[3]

3. I get a sort of frightened feeling as if something awful is about to happen:

Yes definitely and quite badly[3]	Yes, but not too badly[2]	A little, but it doesn't worry me[1]	Not at all[0]

4. I can laugh and see the funny side of things:

As much as I always could[0]	Not quite so much now[1]	Definitely not so much now[2]	Not at all[3]

5. Worrying thoughts go through my mind:

A great deal of the time[3]	A lot of the time[2]	From time to time[1]	Only occasionally[0]

6. I feel cheerful:

Not at all[3]	Not often[2]	Sometimes[1]	Most of the time[0]

7. I can sit at ease and feel relaxed:

Definitely[0]	Usually[1]	Not often[2]	Not at all[3]

8. I feel as if I am slowed down:

Nearly all of the time[3]	Very often[2]	Sometimes[1]	Not at all[0]

9. I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all[0]	Occasionally[1]	Quite often[2]	Very often[3]

10. I have lost interest in my appearance:

Definitely[3]	I don't take as much care as I should[2]	I may not take quite as much care[1]	I take just as much care as ever[0]

11. I feel restless as if I have to be on the move:

Very much indeed[3]	Quite a lot[2]	Not very much[1]	Not at all[0]

12. I look forward with enjoyment to things:

As much as I ever did[0]	Rather less than I used to[1]	Definitely less than I used to[2]	Hardly at all[3]

13. I get sudden feeling of panic:

Very often indeed[3]	Quite often[2]	Sometimes[1]	Not at all[0]

14. I can enjoy a good book, radio or TV programme:

Often[0]	Sometimes[1]	Not often[2]	Very seldom[3]

Thank you for taking the time to fill in this questionnaire. If you have any comments, please write them in the box below:

Thank you for completing this questionnaire. Please give it to the healthcare professional that you see in the clinic.

Study contact details
[insert details of local researcher]

APPENDIX 4: REFERRAL LETTER

Insert local NHS trust logo here

[insert address, telephone and e-mail address for local ESP]

[insert date]

Dear [insert clinician name],

Referral for [insert treatment]

Please find enclosed a referral request for **[insert name and date of birth of patient]**. [Insert patient name] is experiencing long-term pain after total knee replacement and has attended an assessment clinic at 3 months post-operative as part of the STAR randomised trial. The STAR trial is being conducted at 4 centres across the UK (Bristol, Cardiff, Exeter and Oxford) and will involve 380 patients. The STAR trial is evaluating a care pathway for patients with long-term pain after knee replacement. The care pathway involves an assessment by a healthcare professional to identify potential causes for the pain and then referral onto appropriate services.

[Insert patient name] has been assessed today and it is felt based on the assessment that they need the following assessment/interventions in order best address the persistent pain they are experiencing after their knee replacement.

[Delete as appropriate]

Neuropathic Pain

Some of the pain that [insert patient name] has been experiencing has been identified as being neuropathic in nature. We feel therefore that they would very much benefit from a multimodal approach to their analgesia to include an

anti-neuropathic pain medication. We would be grateful if they could please be prescribed Amitryptilline, Gabapentin or Pregabalin for the next 3 months as is most appropriate to combine with their existing medications. If a patient does not well tolerate the first tried prescription please persist with trialling an alternative. If tolerance or compliance is poor then please do initiate an acute referral to pain services to facilitate management of their neuropathic pain.

Complex Regional Pain Syndrome

[Insert patient name] is in considerable difficulty after their knee replacement that requires urgent attention. They are experiencing symptoms consistent with Complex Regional Pain Syndrome and have met formal diagnostic criteria for this diagnosis. Following knee replacement this requires early multimodal intervention from specialist pain services. We would be very grateful if you could please initiate an **urgent** referral to local pain services for assessment and intervention.

Anxiety/Depression

[insert patient name]has met criteria for anxiety and/or depression as assessed by the Hospital Anxiety and Depression scale. This is a common phenomenon in the context of persistent pain following knee replacement. We would be grateful for your further assessment and management of potential anxiety and depression and, if appropriate in the context of the patient's circumstances and comorbidities, consider prescribing a course of appropriate antidepressants/ anxiolytics.

Surgical Factors

[insert patient name]has undergone assessment which has highlighted factors which perhaps warrant more careful and specialist surgical assessment. Factors considered include possibility of infection, malalignment, stiffness, patellofemoral joint issues or instability. We would be very grateful for your further assessment and management as appropriate of this patient who continues to experience moderate to severe persistent pain after knee replacement.

Factors of concern identified are:

Infection Y/N

Malalignment Y/N
Stiffness Y/N
Patellofemoral joint issues Y/N
Instability Y/N

Physiotherapy

It has been identified that [insert patient name] is experiencing persistent pain following knee replacement and it is felt that they would benefit from some additional input from physiotherapy at this stage to try to maximise their function. We would be grateful if they could please be seen and scheduled urgently for additional physiotherapy plus hydrotherapy if available and deemed appropriate.

With regards,

[insert name of local ESP]

Extended Scope Practitioner

APPENDIX 5: CRPS FORMAL CRITERIA CHECKLIST

CRPS diagnostic checklist

A) The patient has continuing pain which is disproportionate to the inciting event ☐

Category		Sign	Symptom
1 'sensory'	*allodynia* (to light touch and/or temperature sensation and/or deep somatic pressure and/or joint movement) and/or *hyperalgesia* (to pinprick)	☐	*hyperesthesia* does also qualify as a symptom ☐
2 'vasomotor'	Temperature asymmetry and/or skin colour changes and/or skin colour asymmetry	If you notice temperature asymmetry: must be > 1°C ☐	☐
3 'sudomotor/oedema'	Oedema and/or sweating changes and/or sweating asymmetry	☐	☐
4 'motor/trophic'	Decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair/nail/skin)	☐	☐

B) The patient has at least one sign in two or more of the categories ☐

C) The patient reports at least one symptom in three or more of the categories ☐

D) No other diagnosis can better explain the signs and symptoms ☐

If tickboxes A, B, C *and* D are ticked, please diagnose CRPS and refer for confirmation of your diagnosis to a named specialist.

Note:

- 'hyperalgesia is when a normally painful sensation (e.g. from a pinprick) is more painful than normal;
- 'allodynia' is when a normally not painful sensation (e.g. from touching the skin) is now painful;
- 'hyperesthesia' is when the skin is more sensitive to a sensation, than normal.
- In category 4 the decreased range of motion/motor dysfunction is not due to pain. It is also not due to nerve damage or a joint or skin problems. This is a special feature in CRPS and is due to a poorly understood disturbed communication between the brain and the limb. A helpful question to assess this feature is: 'If I had a magic wand to take your pain away, could you then move your xxx (e.g. fingers)' many patients will answer with 'no' to that question.

The distinction between CRPS 1 (no nerve injury) and CRPS 2 (major nerve injury) is not required.

About 10% of patients cannot recall any specific trauma, or indeed report that their CRPS developed with an everyday activity such as walking or typewriting. It is appropriate to make the diagnosis of CRPS in these patients.

APPENDIX 6: TELEPHONE PROFORMA FOR INTERVENTION FOLLOW-UP

Star
Support and treatment after joint replacement

Telephone proforma for intervention follow-up

To be completed by a researcher prior to giving the form to the healthcare professional:

Patient name:

Patient telephone number:

Telephone follow-up: 1st ☐ 2nd ☐ 3rd ☐ 4th ☐ 5th ☐ 6th ☐

Date of surgery: ☐☐/☐☐/☐☐☐☐

Months post-operative: ☐☐

Date of clinic appointment: ☐☐/☐☐/☐☐☐☐

Summary of clinic outcome and treatment to date:

To be completed by a healthcare professional during a telephone discussion with the patient. Please refer to the associated SOP for further guidance.

1. Your Initials: ☐☐☐

2. Your job title:

3. Your Band: ☐

4. Today's date: ☐☐/☐☐/☐☐☐☐

5. Duration of telephone call: ☐☐ minutes

6. Has the patient received the treatment they were referred to as part of the STAR care pathway? If not, please describe why:

7a. Does the patient require any further referrals?

Yes ☐ No ☐

7b. If yes, please provide further details

8. Action plan

9. Date next telephone call due: ☐☐/☐☐/☐☐☐☐

10. Comments